85-981

No. ——

Supreme Court, U.S.
FILED
DEC 9 1985
JOSEPH F. SPANIOL, JR.

IN THE

Supreme Court of the United States

OCTOBER TERM, 1985

CONTACT LENS MANUFACTURERS ASSOCIATION,
Petitioner,

v.

FOOD AND DRUG ADMINISTRATION OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,
Respondent.

PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

DANIEL J. MANELLI
Counsel of Record
EDWARD A. SCALLET

THOMPSON & MITCHELL
1120 Vermont Avenue, N.W.
Suite 1000
Washington, D.C. 20005
(202) 857-0350

Attorneys for
Contact Lens Manufacturers Association

PRESS OF BYRON S. ADAMS, WASHINGTON, D.C. (202) 347-8203

QUESTIONS PRESENTED

Does the classification scheme of the Medical Device Amendments to the Food, Drug, and Cosmetic Act (21 U.S.C. 321, *et seq.*)

—incorporate a presumption in favor of the highest level of regulation (Class III status) for medical devices;

—require proponents of classification out of Class III to rebut that presumption by proving that no product meeting the generic description of the device could be unsafe or ineffective; or

—override the general administrative law requirement that the agency's judgment must be based on the administrative record.

TABLE OF CONTENTS

	Page
OPINION BELOW	1
JURISDICTION	2
STATUTES INVOLVED	2
STATEMENT OF THE CASE	4
REASONS FOR GRANTING THE PETITION	9
ARGUMENT	11
A. The Court Below Failed To Articulate An Appropriate Burden Of Proof.	12
B. The Showing Allegedly Required For Reclassification Is Impossible For Any Device.	15
C. The Court Below Failed To Base Its Review On The Administrative Record.	17
CONCLUSION	21

TABLE OF AUTHORITIES

CASES: Page

Almay, Inc. v. *Califano*, 569 F.2d 674 (D.C. Cir. 1977). 11

American Trucking Ass'ns. v. *United States*, 344 U.S. 298 (1953) 13

Association of Data Processing Services Organizations, Inc. et al. v. *Board of Governors of the Federal Reserve System*, 745 F.2d 677 (D.C. Cir. 1984) 11

Camp v. *Pitts*, 411 U.S. 138 (1973) 18

Industrial Union v. *American Petroleum*, 448 U.S. 607 (1980) 9, 11, 12

N.L.R.B. v. *Transportation Management Corp.*, 462 U.S. 393 (1983) 12

Pennsylvania v. *Nelson*, 350 U.S. 497 (1956) 11

State Farm Mutual Auto Insurance v. *Department of Transportation*, 680 F.2d 206 (D.C. Cir. 1982) ... 11

STATUTES AND REGULATIONS:

Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 321 *et seq.* 2

21 U.S.C. 360c 3, 7

21 U.S.C. 360j (*l*)(1) 4

21 C.F.R. 860.120(3)(b) 14

21 C.F.R. 860.130(c) 7

21 C.F.R. 860.130(d) 7

21 C.F.R. 860.7(c) 19

TABLE OF AUTHORITIES continued

MISCELLANEOUS: Page

44 Fed. Reg. 51726 20

45 Fed. Reg. 12682 20

47 Fed. Reg. 3695 15

47 Fed. Reg. 3724 15

47 Fed. Reg. 31130 20

47 Fed. Reg. 53402 2

48 Fed. Reg. 50032 20

H.R. Report No. 94-853, Committee on Interstate and Foreign Commerce, 94th Cong., 2d Sess. 12 (1976) 2, 10, 13, 19

Hearings before the Subcommittee on Oversight and Investigations of the House Committee on Energy and Commerce, No. 97-144, 97th Cong., 2d Sess. (1982) 7, 14

Oversight Report of the Subcommittee on Oversight and Investigations of the House Committee on Energy and Commerce on FDA Implementation of the Medical Device Amendments of 1976, 98th Cong., 1st Sess. (1983) 3, 13

Address by FDA Commissioner D. Kennedy to Health Ind. Mfrs. Association (October 27, 1977), *cited in* O'Reilly, *The Food and Drug Administration* (Shepard Publishing, 1979) Sec. 18.04, n.4 13

IN THE

Supreme Court of the United States

OCTOBER TERM, 1985

No. ——

CONTACT LENS MANUFACTURERS ASSOCIATION,
Petitioner,

v.

FOOD AND DRUG ADMINISTRATION OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,
Respondent.

PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

The Contact Lens Manufacturers Association ("CLMA") hereby petitions for a writ of *certiorari* to the United States Court of Appeals for the District of Columbia Circuit to review the withdrawal by the Food and Drug Administration ("FDA") of a proposal to reclassify rigid gas permeable contact lenses under the Medical Device Amendments of 1976.

OPINION BELOW

The opinion of the United States Court of Appeals for the District of Columbia Circuit (App. 2a)[1] is

---

[1] "App." refers to the separately bound appendix filed in this Court by petitioner.

reported at 766 F.2d 592. The order of the FDA withdrawing its reclassification proposal (App. 26a) is reported at 48 Fed. Reg. 56,778 (1983). The FDA proposal (App. 106a) is reported at 47 Fed. Reg. 53,402 (1982).

JURISDICTION

The opinion of the Court of Appeals for the District of Columbia Circuit was rendered on July 9, 1985. Petitioners filed a Petition for Rehearing which was denied on September 10, 1985 (App. 25a). The jurisdiction of this Court is invoked under 28 U.S.C. 1254.

STATUTES INVOLVED

The relevant provisions of the Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 321 *et seq.* (the "Amendments") are reproduced in App. 156a. The basic purpose of the Amendments is to provide both a reasonable "assur-[ance] that the public is protected from unsafe and ineffective devices" and a regulatory climate where "innovations in medical device technology are not stifled by unnecessary restrictions." *H.R. Report No. 94-853, Committee on Interstate and Foreign Commerce,* 94th Cong., 2d Sess. 12 (1976) (hereinafter referred to as *"House Report."*). At the heart of this system is a three-tiered classification scheme for all medical devices:

> The primary mechanism by which the proposed legislation would distinguish between devices which are simple in design and represent little risk to health and those which are sophisticated and potentially hazardous is a carefully-designed classi-

fication process, similar to that recommended by the Cooper Committee.

House Report 34.

Class I devices are items for which the extensive "general controls" applicable to all devices (in whatever class) are sufficient to provide reasonable assurance of safety and effectiveness.[2] Class II devices are subject to both the general controls and "performance standards." *See* 21 U.S.C. 360c.[3] Class III devices are not only subject to general controls, but also must submit a premarket approval application (PMA) and undergo the time-consuming and expensive approval process before the device may be marketed.

Under the Amendments, the FDA is responsible for assigning all medical devices to their appropriate statutory class. This may take place through an initial classification or through reclassification of a previously classified device. Extensive agency regulations have been published governing these processes. *See* App. 184a. As to some devices, the process of initial classifi-

---

[2] *See* Section 513, 21 U.S.C. 360c. These general controls include provisions relating to adulteration (Section 501); misbranding (Section 502); registration, listing and premarket notification (Section 510); banned devices (Section 516); notification and repair, replacement or refund (Section 518); records and reports (Section 519); and good manufacturing practices (Section 520).

[3] As a practical matter, however, there is currently no significant difference between Class I and Class II devices; FDA has classified a large number of devices into Class II, but has not promulgated any performance standards. *See Oversight Report of the Subcommittee on Oversight and Investigations of the House Committee on Energy and Commerce of FDA Implementation of the Medical Device Amendments of 1976*, 98th Cong., 1st Sess. (1983) (hereinafter referred to as "*Oversight Report*").

cation has been completed and final regulations have been published. As to others, proposed classification regulations are pending.

At the present time, however, certain devices have not been the subject of any proposed or final agency classification. These are the so-called "transitional devices" described in Section 520(*l*)(1) of the Amendments, 21 U.S.C. 360j(*l*)(1). The statute initially placed these devices in Class III without agency action, but also provided that they are subject to reclassification. In such cases, where Class III status arises through operation of the transitional provisions, the reclassification proceeding represents the first opportunity for FDA to make a specific determination as to the appropriate classification.

STATEMENT OF THE CASE

This proceeding involves a type of contact lens, a familiar and important product. The original "hard" contact lenses were made principally of a material called polymethylmethacrylate (PMMA), and have been marketed since the 1950's. The specific class of contact lenses at issue here is known as a rigid gas permeable lens (hereinafter referred to as "RGP lens").[4] This lens consists of a plastic which is defined

---

[4] The RGP lenses involved in the decision below and this petition are made from a polymer known as polyacrylate silicone. The original reclassification proceeding also involved lenses made from another polymer (known as "CAB"). In view of the relative unimportance of CAB as contrasted to polyacrylate silicone in the manufacture of RGP lenses, petitioner did not seek court review of the FDA's actions insofar as they pertained to CAB lenses.

Another family of lenses exists, the so-called "soft" or hydrophilic contact lens, made principally of a material called hydroxy-

as chemically and physically stable, optically clear, nontoxic, nonallergenic, and not supportive of bacterial growth. RGP lenses constitute approximately one-fifth of the estimated five million hard lenses in circulation. The remaining hard lenses are PMMA.

The RGP lens material results from a combination of silicone and the basic PMMA polymer. The resulting material retains the optical qualities and resistance to bacterial growth of the PMMA lens, but allows oxygen to diffuse through the lens structure, thus promoting greater comfort and corneal health. There is no dispute in the ophthalmic community or at FDA that RGP lenses are far superior to ordinary PMMA lenses.

Despite the fact that RGP lenses are simple devices, present little risk to health, and have not been associated with adverse reactions, they are regulated at the highest level provided by the Amendments. In contrast, the PMMA lens has been proposed by FDA for inclusion in Class II. As a result, a PMMA lens need not go through the premarket approval process, while the premarket approval requirements of Class III imposed on RGP lenses are estimated to cost $750,000 to $1,000,000. Because of the predominance of small

---

ethyl methacrylate (HEMA). This family of lenses is not at issue in the present proceeding. This proceeding is further limited to daily wear, as opposed to extended wear, contact lenses. Daily wear lenses are to be used only during the wearer's waking hours whereas extended wear lenses are approved by FDA for continuous wear for up to 30 days without removal.

Accordingly, unless otherwise noted, the terms "contact lens", "lens", and "RGP contact lens" as used in this petition refer to a spherical, rigid gas permeable daily wear contact lens made of polyacrylate silicone.

laboratories in the field of contact lenses, this extreme regulatory cost resulted in only one approval of an RGP lens between 1979 and 1983.

This proceeding had its inception in 1980, when representatives of the CLMA approached FDA for appropriate resolution of the regulatory status of the RGP lens. FDA staff suggested that CLMA file a petition to reclassify, and offered to assist in its preparation. After substantial FDA input, CLMA filed a petition to reclassify on March 2, 1981.

FDA referred the petition to its own Advisory Panel, which unanimously recommended reclassification subject to the furnishing of certain additional information. On June 11, 1981, CLMA submitted an amended petition incorporating the information in question, and the Panel reiterated its unanimous recommendation for formal FDA approval.

On August 27, 1981, the chief of FDA's Biological Sciences Branch (to which the CLMA petition had been assigned) concurred in the recommended approval. His memorandum noted that comments on the petition from the public at large had been "thoroughly reviewed by the staff" and the

> [c]onsideration of the regulatory, administrative, technical, and economic issues involved in this matter indicates that significant positive benefits will be realized from this decision while no concommittant [*sic*] negative effects exist . . .

In the ensuing weeks, FDA continued to assure the CLMA that the reclassification process was being completed. The processing of CLMA's petition came to an abrupt and unexplained end, however, in October of 1980. Shortly thereafter, FDA published a Notice

of Intent announcing that it would neither approve nor deny the CLMA's petition, would not publish the panel's recommendation concerning it, and considered it moot (App. 145a).[5] The notice affirmed that the agency deemed CLMA's objectives to be meritorious and would itself initiate a proceeding to reclassify daily wear RGP contact lenses.

Six months then elapsed without even a proposal, much less a final rule. On July 16, 1982, FDA representatives appeared before a Subcommittee of the House of Representatives and were asked about the RGP lens reclassification. The acting Director of the FDA Bureau of Medical Devices conceded that it was "hard to justify" the time FDA had already taken to issue its proposal. *Hearing before the Subcommittee on Oversight and Investigations of the House Committee on Energy and Commerce,* No. 97-144, 97th Cong., 2d Sess. 30 (1982) (hereinafter referred to as *"Oversight Hearings"*). He confirmed, however, that there was no doubt in his mind about the safety and effectiveness of the lenses, or "any in the mind of our scientists." *Id.* at 31.

On November 26, 1982, more than one year after its Notice of Intent, FDA published its proposal to reclassify RGP lenses (App. 145a). FDA stated that reclassification must be based on "valid scientific evidence" which is publicly available (that is, is not from confidential information submitted by manufacturers

---

[5] Publication of the advisory panel's recommendations is required by Section 513(e) of the Act (21 U.S.C. 360c(e)) and the agency's regulations (21 C.F.R. 860.130(c)). Approval or denial of the petition was, similarly, required by 513(e) of the Act and agency regulations (21 C.F.R. 860.130(d)). *See* App. 145a.

in the premarket approval process). Such evidence was found in a series of scientific studies and the absence of any reports of serious adverse effects on health from the "substantial numbers [marketed] in this country." FDA also noted that 50 of the 51 comments received in response to its prior Notice of Intent were favorable.

The administrative record contains comments from hundreds of persons, test data, patent applications, scientific articles, transcripts of oral testimony, reports from scientific, medical and governmental organizations, etc. The overwhelming majority of this record supports reclassification. There is no evidence that RGP lenses are life supporting or sustaining, or present "a potential unreasonable risk of illness or injury"—the criteria Congress established for class III status. There is no evidence to disparage the safety or efficacy of RGP lenses, nor is there evidence that RGP lenses meet the statutory class III definition.

On December 23, 1983, FDA announced the withdrawal of its proposal and termination of the proceeding. The stated reason for the withdrawal of the proposal was a lack of evidence—or at least a lack of the right kind of evidence—to prove that all RGP lenses that could be manufactured in the future would be safe and effective. Believing the withdrawal to be not only contrary to the administrative record and FDA's historical regulatory approach to medical devices, but also based on a patently impossible standard, CLMA initiated this legal proceeding.

REASONS FOR GRANTING THE PETITION

This is a case of first impression. It directly presents the most fundamental legal questions applicable to the classification scheme of the Medical Device Amendments of 1976: burden of proof, nature of evidence required, and the standard that must be met. Thus, the decision in this case will dramatically affect the pace of innovation in medical technology.[6]

The court below was sympathetic to CLMA's case and troubled by FDA's rejection of evidence and use of inconsistent rationales. It nevertheless failed to require that FDA's action be supported by adequate reasoning and appropriate findings. Absent these, administrative decisions cannot be sustained on review. *Industrial Union* v. *American Petroleum,* 488 U.S. 607 (1980). The court below adopted, *sub silentio,* a permissive standard of review that makes FDA's classification decisions essentially unreviewable.

More troubling is the court's interpretation of the legal standards applicable to classification and reclassification. Under the contradictory and illogical rationale eventually devised by FDA in this proceeding, any classification outside of Class III is impossible. In fact, FDA has for years before and since its decision here used vastly different standards in classifying and reclassifying other medical devices.

---

[6] There is no dispute as to the profound consequences of the agency's refusal to reclassify daily wear RGP lenses. FDA itself affirmed that reclassification "would have resulted in increased competition, decreased costs, and an increase in employment and also would have allowed small contact lens firms to compete in the world market." (App. 104a)

The manufacturing and marketing of medical devices is a subject of profound importance to the public health and welfare. The classification process whereby devices are assigned to their appropriate level of regulatory control is central to the Medical Device Amendments of 1976. The legislative history refers to the process as the "primary mechanism" for distinguishing between simple devices presenting little risk to health, and sophisticated life supporting devices which are potentially hazardous (*House Report* 34).

If arbitrary and capricious agency actions distort this mechanism by imposing the highest level of regulatory costs on products not meeting statutory criteria for such treatment, the medical device marketplace may become the sole domain of those large corporations which can meet the resulting exorbitant regulatory costs. Far from promoting the public safety, such arbitrary decisionmaking commits scarce agency resources to inappropriate processing of essentially innocuous devices with consequent dilution of effort in more pressing areas. Moreover, the elimination of small device manufacturers from the marketplace will also eliminate much of the innovation which has characterized the medical device industry.

CLMA has spent five years and a substantial portion of its resources attempting to comply with the capricious commands of FDA. In view of the court's opinion, it is unlikely that other small manufacturers will ever make a similar attempt. In short, if the Court does not grant *certiorari* in this case, it is likely that the decision below will govern the classification process, and the pace of innovation in medical technology, for a considerable time into the future.

ARGUMENT

The validity of an agency's determination must be judged on the basis of the agency's stated reasons for making the determination; they cannot be made up by a reviewing court. *Industrial Union* v. *American Petroleum, supra.* FDA, in particular, must provide a thorough and comprehensive statement of the reasons for its decision. *Almay, Inc.* v. *Califano,* 569 F.2d 674 (D.C. Cir. 1977) at 701. That is not present here. While the agency's withdrawal notice is voluminous, it is devoted almost entirely to a determined effort to refute the administrative record. Whether the standard of review is the "substantial evidence" standard or the "arbitrary and capricious" standard, this course of action is not permissible. *State Farm Mutual Auto Insurance* v. *Department of Transportation,* 680 F.2d 206 (D.C. Cir. 1982); *Association of Data Processing Services Organizations, Inc. et al.* v. *Board of Governors of the Federal Reserve System,* 745 F.2d 677 (D.C. Cir. 1984), and cases cited therein.

The court below, while recognizing "substantial merit" in petitioner's arguments, nevertheless chose to defer to FDA, even to the point of suggesting rationales not advanced by the agency itself. Elsewhere in the decision, the illogical consequences of the agency's action and its inconsistencies with prior agency determinations were attributed to "ironies effected by the statute."

Petitioner submits that the court below failed to apply the statute in a logical manner so as to carry out the Congressional intent. *Cf. e.g. Pennsylvania* v. *Nelson,* 350 U.S. 497 (1956). Specifically, a proper interpretation of the device classification scheme would

not yield the inconsistent and irrational results involved in the decision below.

A. The Court Below Failed To Articulate An Appropriate Burden Of Proof.

As set forth below (*see* pp. 18 to 21, *infra*), neither the FDA nor the court below challenge CLMA's assertion that the administrative record in this case is overwhelmingly one-sided in favor of the reclassification of RGP lenses. The court, however, sanctioned the agency's rejection of the record by holding that CLMA had failed to provide enough information to meet its "burden of proof." The burden, as articulated by FDA and sustained by the court below, was:

> "[T]he burden of proof that reclassification is appropriate is on FDA and those who support reclassification, *regardless of whether those opposing reclassification can or do submit evidence showing that reclassification is not appropriate.*" (App. 45a, emphasis added)

Thus, the proponents of reclassification were assigned a burden of persuasion which, by its terms, could never be shifted to the other side—without regard to whatever evidence the proponents might present, and regardless of whether the other side presented anything at all. Such an allocation of the burden of proof is clearly unreasonable and goes far beyond those allocations which this Court has found justified in other cases; see *Industrial Union* v. *American Petroleum, supra*, 448 U.S. at 657 (Secretary of Labor exceeded his authority in imposing burden on industry of proving the existence of a safe level of benzene exposure); see also, *N.L.R.B.* v. *Transportation Management*

Corp., 462 U.S. 393 (1983) at 403; and *American Trucking Ass'ns.* v. *United States*, 344 U.S. 298 (1953) at 318-19. As will be shown (*see* pp. 15-17, *infra*), the burden assigned to the petitioner was, by its terms, impossible to carry.

The purpose of a classification or reclassification proceeding is to assign the appropriate level of regulatory control. There is no presumption in favor of any of the three classes. With regard to Class III, the statute provides a limited definition. Because the premarket approval process is so expensive, and its effect on innovation in technology so drastic, Congress limited Class III to those devices which are either (1) used for the supporting or sustaining of human life; or (2) present a potential unreasonable risk of illness or injury. As the legislative history provides:

> [This] requirement will assure that premarket approval does not become a routine requisite for all devices, while still providing the Secretary with ample latitude to classify a device into class III in instances in which its use poses public health concerns.

House Report 35. In short, Class III is "reserved for the most risk-laden devices" (*Oversight Report* 6)—to date, approximately one percent of the classification proceedings have resulted in a finding of Class III status. *Oversight Report* 14.[1]

---

[1] "The device law is selective, focusing more attention on the potentially hazardous devices than the others. And even those devices constitute but a small segment—five percent—of the universe of devices." Address by FDA Commissioner D. Kennedy to Health Ind. Mfrs. Association (October 27, 1977), *cited in* O'Reilly, *The Food and Drug Administration* (Shepard Publishing, 1979) Sec. 18.04, n.4.

The court below, however, uncritically accepted FDA's presumption of class III status. It stated that "[w]e cannot fault the FDA's assignment of the burden of proof to those seeking to change the status quo" (App. 15a). But, the statute itself imposes no such burden and FDA regulations provide that the criteria for classification and reclassification are precisely the same. *See* 21 C.F.R. § 860.120(3)(b) (App. 202a). Since RGP lenses are maintained in class III status only through operation of the transitional provisions, the instant proceeding was, like initial classification, the first occasion for a reasoned determination of the appropriate regulatory class for RGP lenses.

The record here is devoid of any threshold finding that RGP lenses meet the statutory definition, or historical agency identification, of a class III device. There is no evidence that RGP lenses are life-supporting, or sustaining, or hazardous devices; there is conclusive evidence that they are not. Under those circumstances, any possible burden of proof should shift to those asserting the need for class III regulation. It was plain error for the court to invent a presumption of Class III status in the face of the heretofore consistent agency interpretation of the statute.[8]

---

[8] The Court may get a sense of the arbitrariness of this decision by comparing FDA's treatment of RGP lenses here with its reaction to super-absorbent tampons and toxic shock syndrome. In the same Oversight Hearings in which FDA officials assured the industry and Congress that its scientific and policy personnel were united behind reclassification, then-Commissioner Hayes emphasized the effectiveness of general controls to respond even to severe health crises such as toxic shock syndrome by requiring warnings on tampon packages. Tampons, even super-absorbent ones, are Class II devices. *Oversight Hearings* 7.

B. The Showing Allegedly Required For Reclassification Is Impossible For Any Device.

The organizing principle of the Medical Device Amendments is to group devices by, in the words of FDA's regulations, "generic types." Risks presented and benefits gained can only be evaluated with respect to those generic categories. As FDA has recognized:

> It is not practical for FDA to publish an identification of each type of device that is so detailed as to anticipate every product feature that may be relevant.

47 Fed. Reg. 3695 (January 26, 1982).

Nevertheless, the FDA denied reclassification here on the basis that the proponents allegedly could not provide a generic definition of RGP lenses such that no conceivable molecular variant which might be covered therein would be unsafe or ineffective. This assigned to the proponents the patently impossible task of devising the very type of definition which the agency itself acknowledges is impractical.

The court below permitted this articulation of an impossible requirement to go unchallenged. Instead, the court below adopted the FDA's *ad hoc* standard: that the proponents of reclassification must affirmatively prove that "*any* RGP lens a manufacturer *might* create will meet the statutory requirements." (App. 18a; emphasis added.)* Obviously, no evidence, as to

---

* The attempt of the court below to supply its own rationales to explain prior inconsistent determinations by FDA was most unfortunate. Specifically, among hundreds of available examples, petitioner drew attention to the agency's determination that the artificial eye should be placed in class II (47 Fed. Reg. 3724). FDA's

any device, could possibly prove that another device of the same generic description which a manufacturer "might" create in the future would comply with statutory requirements.[10]

The error of the court below was to confuse the concepts of classification and adulteration. Specifically, the concept of device classification is distinct from the underlying requirement of the Act that all medical devices must have a reasonable assurance of safety and effectiveness. The law requires all medical devices,

---

definition states only that the device is "usually made of glass or plastic." Clearly this generic description does not assure that "any [artificial eye] a manufacturer might create will meet the statutory requirements," (*compare with* App. 18a). The court below offered the patently implausible rationale that since artificial eyes only "stand in" for a lost eye, they may be appropriate for less "circumspect" regulation than the RGP contact lens which is in contact with the eye (App. 22a). Thus, as the court below would have it, FDA was consistent in determining that an RGP lens is appropriate for class III despite the fact that an artificial eye made of identical plastic material, inserted into the orbital socket where it is in prolonged and intimate contact with living tissue in a location where injury to the body might well go undetected for a significant period of time, is appropriate for class II.

[10] The court acknowledged that FDA could not have applied this standard in its proposed classification of PMMA lenses into class II (App. 22 *et seq.*). It suggested, however, various explanations that have no basis in fact or the record, finally suggesting that the proposal might not be made final (App. 24a). The opinion suggests (App. 23a) that "by the year 2000" there should be sufficient accumulated market experience to permit reclassification of RGP lenses. This apparently reflects the court's expectation that the store of knowledge will then equal what is now known about PMMA lenses. But, even in the year 2000, only a small fraction of the conceivable variants of RGP lenses will have been marketed, and the FDA's rationale would still preclude reclassification.

regardless of statutory class, to meet these safety and effectiveness requirements. A device which is unsafe and/or ineffective is legally adulterated and subject to immediate regulatory action under the extensive general controls provided by Congress for such cases. All devices, regardless of class, are potentially subject to adulteration. This can arise, among other things, through the use of unsafe materials which come into contact with the body or utilization of maladroit design (*e.g.* a crutch which fractures when weight is placed upon it). The possibility of adulteration does not mean that the device must be placed in Class III.

No generic description of any device, and no amount of evidence, can be "[t]aken as proof that any [device] a manufacturer might create will meet the statutory requirements." Put simply, no evidence can preclude at least the possibility that some manufacturer may some day adulterate a device. By suggesting that such a showing is required for reclassification the court below fell into a basic error.

Petitioner submits that the assertion of the need for an impossible demonstration is contrary to the statute, is arbitrary and capricious, and should not have been sustained.

C. The Court Below Failed To Base Its Review On The Administrative Record.

In the previous section, petitioner has referred to the assertion of an unjustified burden of proof against it on the basis that it sought reclassification out of Class III (*i.e.*, sought "to change the status quo"; App. 15a), and the definition of that burden in terms insuring that it could never be met. This provided an

expedient for the agency to avoid the administrative record.

As this Court has held, howe[illegible]he focal point for judicial review should be the administrative record." *Camp* v. *Pitts*, 411 U.S. 138, 142 (1973). The court below nevertheless approved the agency's wholesale disparagement of the record. This was despite the court's obvious misgivings over the failure of the FDA to acknowledge any of the massive administrative record as valid scientific evidence supporting reclassification. See App. 16a to 17a, characterizing the FDA position as "unsettling," "somewhat numbing," "remarkable," and based on "limited-purpose agnosticism." The fact is that the record contains the following items not credited by FDA or the court below:

—The finding by FDA that RGP lenses present, at worst, minor risks to health;[11]

—The unanimous recommendation of FDA's expert advisory panel;[12]

—Data from clinical investigations;[13]

---

[11] FDA stated that it had "searched diligently for evidence of serious, irreversible adverse effects . . . and found no such evidence." App. 47a.

[12] FDA has, in other classifications, relied heavily—and in fact *exclusively*—on the recommendations of its advisory panels. *See* p. 20, *infra*.

[13] The court below could not explain how FDA could "disparage[] . . . the same studies it had once acclaimed" between the proposal and withdrawal. *See* App. 16a. It did excuse FDA's rejection of two large-scale studies (involving well over 100,000 patients) on the ground that the clinical data had been submitted in PMA applications which are, by statute, promised confidentiality for purposes of reclassification. *See* App. 17a. The court termed

—Evidence from the experience with RGP lenses;[14] and

—Expert opinion proferred by a wide spectrum of scientific, medical and professional individuals and organizations.[15]

The court below improperly sanctioned FDA's assertion that this evidence did not rise to the level of valid scientific evidence. The legislative history and the agency's regulations clearly show that this is precisely the type of evidence which Congress intended the agency to consider.[16] This is, moreover, exactly the type

---

this a "conundrum" set up by a statutory provision without acknowledging that the provision was irrelevant here because the manufacturers of those two lenses waived the confidentiality of their data, and it is all part of the public record. It is an obvious error to interpret the confidentiality provision to prohibit waiver by the manufacturer involved.

[14] The FDA proposal noted that RGP lenses "have been marketed in substantial numbers in this country, and they have been shown to be safe and effective," (App. 121a). This "marketing experience" test outlined in the proposal was supported by the absence of reports of problems on FDA's Device Experience Network and research from the primary liability insurers that there have been *no* contact lens-related claims.

[15] Among the organizations which commented favoring reclassification were the American Academy of Ophthalmology and the American Optometric Association. Literally hundreds of individual optometrists, ophthalmologists, manufacturers, chemists, engineers, opticians, and others with a combined thousands of years of experience with RGP lenses uniformly supported reclassification.

[16] *See House Report* 40 (evidence for classification "should also consist of less formal evidence, other scientific information, or judgment of experts, when available"); 21 C.F.R. § 860.7(c) (regulation defines valid scientific evidence to include "reports of

of evidence upon which FDA has repeatedly relied in classifying virtually every other device.[17] In fact, responding to criticism that it "relied too heavily on panel experience and expertise" FDA has stated:

> It is apparent from the statute and from the legislative history of the . . . Amendments . . . that Congress intended FDA to rely on the advice of its device classification panel in deciding how to classify devices.[18]

More fundamentally, the rejection of expert judgment underscores once more the court's misconception of the classification process. Petitioner does not deny the relevance of clinical investigation—it supplied reports of over 1200 clinical trials and proof that RGP lenses are probably the most thoroughly tested devices in the history of FDA regulation—but that evidence cannot answer the most important questions posed by classification. As noted, the process is not designed to require conclusive proof that every possible device in a category will always be safe and effective. Rather, the purpose of the classification proceeding is to determine the appropriate level of regulation, and that question in turn calls primarily for the exercise of regulatory judgment. The views of experts on such important questions as the basic chemical and physical

---

significant human experience with a marketed device, from which it can fairly and responsibly be concluded by qualified experts that there is reasonable assurance of the safety and effectiveness of a device under its conditions of use.") (App. 192a-193a).

[17] See, for example, classifications of anesthesiology devices (47 Fed. Reg. 31130), obstetrical devices (45 Fed. Reg. 12682); and physical medicine devices (48 Fed. Reg. 50032).

[18] 44 Fed. Reg. 51726 (concerning classification of neurological devices).

nature of the device, the conditions under which it is used and marketed, the benefits to be gained, and the effect on the future progress of the medical technology involved, are all relevant to the formation of that judgment.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

DANIEL J. MANELLI
Counsel of Record
EDWARD A. SCALLET

THOMPSON & MITCHELL
1120 Vermont Avenue, N.W.
Suite 1000
Washington, D.C. 20005
(202) 857-0350

Attorneys for
Contact Lens Manufacturers Association

December 1985